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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,570	09/15/2003	Luc R. Mongeon	1023-203US01	2842

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SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
01/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairdocketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/663,570	MONGEON ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-24,26,29-33,35-42 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24,26,29-33,35-42 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 21-24, 26, 29-33, 35-42 and 46 are rejected under 35 U.S.C. 103(a) as obvious over Soykan in view of Heil, Jr. et al. (US 4,819,662, hereinafter "Heil") and Girouard et al. (US 2004/0158289, hereinafter "Girouard").

4. In regards to claims 21, 24, 36, and 46, Soykan discloses a method/system comprising a lead for delivering electrical stimulation to tissue (col. 13, line 38) and eluting genetic material from a polymeric matrix (col. 11, line 1) to cause transgenic expression that increases the conductivity at the stimulation site. Increasing the contractile ability of the stimulation area (from cells that do not contract at all, per

column 1, lines 57-58, to cells that contract, per the abstract of the disclosure) inherently increases the conductivity because non-contractile cells do not have the membrane proteins that allow for cell contraction, while contractile cells do have these proteins. This inherent and fundamental feature of these cells means that the conductivity is increased in the region of these new cells. Further, this increase in contractile ability inherently creates some preferential conduction pathway between the stimulation site and at least one of a bundle of His or a Purkinje fiber because the applied pulse or propagating action potential must follow some preferred path created by the improved conductivity of the treated region of the heart. For example, referring to Figure 1, after treatment, action potentials generated in the newly treated region will flow through a different path than when the tissue was not fully-functioning contractile heart tissue. Soykan does not disclose a chamber that elutes material from a porous electrode or that the genetic material causes expression of connexin or a gap-junction. Heil teaches of providing a lead with a removable chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of electrical therapy (abstract, Fig. 7). Further, Girouard teaches providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue (par. 0146). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Soykan's invention by providing a lead with a chamber that elutes substances through a porous electrode for the purpose of providing controlled release of pharmacological agents at the site of

electrical therapy and providing a cardiac therapy comprising delivering connexin for the purpose of repairing damaged heart tissue.

5. In regards to claims 22, Soykan discloses that the matrix is extracellular collagen (col. 11, line 47).

6. In regards to claims 23 and 37, the matrix is cross-linked (col. 11, line 55). The level of cross-linking is inherently proportional to the release rate.

7. In regards to claims 26, the delivery vector is a liposome (claim 7).

8. In regards to claims 32, the electrode is implantable (col. 13, line 49).

9. In regards to claims 33, the tissue is cardiac tissue (abstract).

10. Claims 36 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soykan in view of Heil and Girouard. Soykan's modified invention discloses the essential features of the claimed invention, including using autologous biological material (col. 5, line 67) that is incorporated just prior to delivery by swelling the hydrogel (col. 11, line 59), but does not disclose a freeze-dried (lyophilized) or frozen matrix, a genetic material that causes expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent, placing the matrix in the lead just before implantation, or soaking of the distal end of the lead in the genetic material. It is well known in the art to freeze-dry or freeze matrix to increase the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to reduce rejection complications in a host patient, and to soak (or swell) matrix in genetic

material before placement into the body (either before delivery, or right at delivery) to allow autologous biological substances to be implanted. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Soykan's invention by freeze-drying or freezing matrix to provide the predictable result of increasing the shelf-life of the biologically active substance, to provide genetic materials that cause expression of a metalloproteinase, an anti-inflammatory agent, or an immunosuppressant agent to provide the predictable result of reducing rejection complications in a host patient and soaking matrix in genetic material before placement into the body to provide the predictable result of allowing autologous biological substances to be implanted.

Response to Arguments

11. Applicant's arguments filed 11/7/2008 have been fully considered but they are not persuasive. Applicant argued that the combination of Soykan, Heil, and Girouard lacks a reasonable expectation of success because Heil only discusses a matrix that elutes a drug and that drugs and genetic material are different and may have different properties and effects. The Examiner agrees that drugs and genetic material are different and may have different effects, but the Examiner also takes the position that these differences in therapeutic effect do not pertain to the mechanical diffusion of these substances from a porous electrode. As the electrode is porous enough to allow for "free fluid flow" (col. 2, lines 30-43), the Examiner takes the position that this electrode is capable of eluting both drugs and genetic material.

12. Applicant also argued that the motivation to modify Soykan with Heil's teaching (to provide controlled release of a pharmacological agent) lacks rational underpinning because Soykan already teaches controlled release, and there is no indication that the porous electrode is advantageous over the coating disclosed by Soykan. However, the test for obviousness does not require a teaching, suggestion, or motivation. The Examiner maintains the rejection on the grounds that modifying Soykan's genetic material-eluting cardiac device with Heil's known prior art drug-eluting cardiac device is a simple substitution of one known element for another to obtain the predictable results of controlled release of a therapeutic substance. *See KSR International Co. v.Teleflex Inc. (KSR),* 550 U.S. ___, 82 USPQ2d 1385 (2007).

13. Likewise, Applicant's argued that causing the expression of connexin for the purpose of repairing damaged heart tissue, as taught by Girouard, lacks rational underpinning because there is no suggestion or motivation to modify the genetic material used by Soykan. However, the Examiner maintains the rejection on the grounds that modifying Soykan's cardiac-repairing genetic material with Girouard's known prior art cardiac-repairing genetic material is a simple substitution of one known element for another to obtain the predictable results of repairing damaged heart tissue.

14. In regards to claim 24, the Office Action of 8/7/2008 indicated the claim as rejected under Soykan, Heil, and Girouard, and Heil clearly shows the feature in Figure 7 and describes the feature in the abstract of the disclosure. Further, this limitation was more specifically addressed in the Office Action of 8/27/2007.

15. As indicated above, the Examiner takes the position that the subject matter of new claim 46 is an inherent feature of Soykan's invention. Because Soykan is in effect creating new contractile tissue around the stimulation device, this inherently creates a new arbitrary "preferred conduction pathway."

Conclusion

16. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762